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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/229,324	01/13/99	HIEI	Y 760-262P

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EXAMINER

BENZION, G

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/229,324

Applicant(s)

Hlei et al.

Examiner

Gary B nzlon, Ph.D.

Group Art Unit

1638



☒ Responsive to communication(s) filed on 8 Sep 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-16 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Status of the Application

Claims 1-16 are pending.

Detailed Action

Basis for Non-statutory Double Patenting (Obvious and Non-Obviousness Type)

The non-statutory double patenting rejection, whether of the obvious-type or non-obviousness type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F. 2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending application Serial No. 08/428,238. Although the conflicting claims are not identical, they are not patentably distinct from each other because both application are drawn to a method to transform monocotyledonous plants, in particular rice, by *Agrobacterium*. The instant application is drawn to a method in which an explant is infected, and thus transformed, on dedifferentiation-inducing medium for 1 to 6 days while the copending case transformation is mediated to explants which have not be treated for dedifferentiation. The phrase "1 to 6 days," however, is seen to encompass a time period of in which no dedifferentiation has taken place and as such would be the equivalent step claimed in the copending case. Accordingly, the applications encompass a single inventive concept and thus one invention.

35 U.S.C. 112

The following is a quotation of the first paragraph of 35 § U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Potrykus (pages 535, 538-542) assess the realities and possibilities of various method of plant/cell transformation. Under the section Proof and competence he sets forth the evidence that a person having skill in the art would consider as convincing of the production of a stable transformed whole transgenic plant, regardless of method. The evidence considered necessary is:

- 1) Serious controls for treatments and analysis
- 2) A tight correlation between treatment and predicted result.
- 3) A tight correlation between physical (Southern blot, *in situ* hybridization) and phenotypic (enzyme assay data).
- 4) Complete Southern analysis containing (a) the predicated signals in high molecular weight DNA, in hybrid fragments between host DNA and foreign gene, and the complete gene and (b) evidence for the absence of contaminating DNA fragments or the identification of such fragments.
- 5) Data that allows discrimination between false positives and correct transformations in the evaluation of physical and phenotypic evidence with transmission to sexual offspring, as well as genetic and molecular analysis of offspring populations.

The instant specification fails to meet the standards set forth above. First, although the method as claimed is directed to the transformation of a monocotyledonous the preponderance of the evidence does not support this goal. For example, at page 30, at line 20 et seq. of the specification Applicants state:

Although the shoot apex tissue exhibited high rate (sic) of introduction of GUS gene (sic) after the culture with the *Agrobacterium* strain, after the selection by hygromycin, all tissue died and no tissue resistant to hygromycin were obtained.

Clearly the inability to recover "transgenic tissue" which expressed the gene of interest would indicate that claimed method requires a high level of skill, that is, skill beyond that commonly found in the art which, when viewed in consideration of the Forman factors (*Ex parte Forman*, 230 USPQ 546 (BPAI 1986)) teaches that the invention is not enabled. This conclusion is amplified by the data presented at page 31, first full paragraph, which teaches that scutellum calli and suspension cells, which were transformed, failed to produce resistant cells from the scutellum samples. Furthermore, at page 42, evidence is presented that using Southern blots indicated the presence of a 5.5 and 6 Kb fragment. The latter fragment is alleged

to be indicative of chromosomal integration as high molecular weight DNA. A band of 6 Kb is too small to be indicative of genomic (chromosomal) DNA. This is taught by Langridge et al.¹ in which the presence of DNA hybridization in undigested DNA was smaller than that of genomic DNA. These data are also presented in summary tables with no actual evidence of the actual positive Southern blots, such as photomicrographs of the actual Southern' with appropriate controls. The evidence presented for rice, beginning at page 58, is similarly incomplete evidence of transformation. Finally, Schlappi et al.² in comparing the use of *Agrobacterium* transformation via agroinfection, notes that undifferentiated meristematic tissue of very young immature maize embryos (10 to 14 DAP), were not competent for agroinfection. These results suggested early stage embryos fail to induce *Agrobacterium vir* genes (@9, right col.) and that some degree of dedifferentiation was necessary to induce the *Agrobacterium vir* genes. This teaching is in direct conflict with the claimed method. Similarly, the work of Hiei et al. (US Patent 5,591,616) would indicate that dedifferentiation was necessary to allow *Agrobacterium* to infect and transfer the Ti DNA in monocots and that genotype play an determining role in infection (@11, left col.). The vector used in Hiei et al., and that claimed herein, are the same vector. Attention is directed to US patent No. 5,591,616 a sample of which is cited below:

Further, by employing a **super binary vector**, it was first attained to introduce genes with high efficiency into varieties which are difficult to culture such as a variety of rice. Still further, as will be described in the examples below, by employing an appropriate selection method after inoculation, the chimera phenomenon in which the desired gene is introduced chimerally can be decreased.

Agrobacterium tumefaciens A281 exhibiting extremely high transformation efficiency (Hood E. E. et al., 1984; Bio/Technol. 2:702-709, Hood E. E. et al., 1986; J. Bacteriol. 168:1283-1290, Komari T. et al., 1986; J. Bacteriol. 166:88-94, Jin S. et al., 1987; J. Bacteriol. 169:4417-4425, Komari T. 1989; Plant Science 60:223-229 ATCC37394) (Japanese Laid-open Patent Application (Kokai) No. 4-222527. In this specification, this vector is also called "**super binary vector**"). **Such a super binary vector may preferably be employed in the present invention.** [Emphasis in original].

Accordingly the claimed invention is not enabled to the extent that it teaches the person having skill in the art how to make and use the invention.

¹ Langridge et al. The Plant Journal (1992) 2(4), 631-638.

² The Plant Cell, Vol. 4, 7-16. Cited by Applicants in US Serial # 08/428,238.

Summary

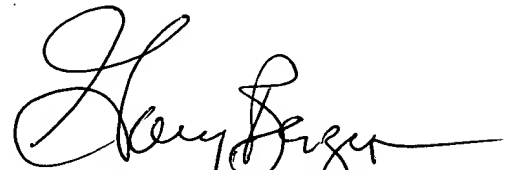
No claim is allowed.

Inquires

Any inquiry concerning this or earlier communication from the examiner should be directed to Gary Benzion, Ph.D. whose telephone number is (703) 308-1119. The examiner can normally be reached on Monday-Friday from 7:00 AM to 3:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703)-308-4310. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Benzion
10/02/00



GARY BENZION, Ph.D.
PRIMARY EXAMINER
GROUP ART UNIT 1638